H. R. 220

To provide for a national strategy to address and overcome Lyme disease and other tick-borne diseases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 2019

Mr. Smith of New Jersey (for himself, Mr. Peterson, Mr. Posey, Ms. Stefanik, Mr. Fitzpatrick, Mr. Sires, Ms. Pingree, and Mrs. Hartzler) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for a national strategy to address and overcome Lyme disease and other tick-borne diseases, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Lyme and Tick-Borne Diseases Control and Accountability Act of 2019”.

SEC. 2. OFFICE OF OVERSIGHT AND COORDINATION FOR TICK-BORNE DISEASES.

(a) Establishment.—The Secretary of Health and Human Services shall establish in the Office of the Secretary the Office of Oversight and Coordination for Tick-Borne Diseases, to be headed by a director appointed by the Secretary—

(1) to oversee the creation and updating of an integrated national strategy to overcome Lyme disease and other tick-borne diseases; and

(2) to oversee and coordinate Lyme disease and other tick-borne disease programs and activities across the agencies and offices of the Department of Health and Human Services.

(b) Objective of Office.—In carrying out subsection (a), the Director of the Office shall facilitate and work to ensure accomplishment of the following activities:

(1) Expansion and enhancement of epidemiological research and basic, translational, and clinical biological and biomedical research.

(2) Expansion and improvement of the surveillance and reporting of Lyme disease and other tick-borne disease, including coinfections with agents of more than one tick-borne disease.

(3) Development of effective diagnostic tests to accurately and timely diagnose Lyme disease and
other tick-borne disease, including direct detention tests.

(4) Development of treatments to cure or improve the lives of those who are infected with Lyme disease or other tick-borne disease or who suffer from a tick-induced disorder.

(5) Design and conduct of clinical trials of sufficient size and duration to support clinical recommendations.

(6) Development and maintenance of one or more registries of patients and their experiences relating to exposure to, diagnosis for, and treatment of tick-borne disease, including outcomes, which registries shall protect the confidentiality and safety of patient data.

(7) Systematic documentation of the experiences of health care professionals in diagnosing and treating tick-borne disease, including diagnostic and treatment outcomes.

(8) Inclusion of individuals with chronic Lyme disease in clinical, research, and service efforts.

(9) Coordination with international bodies to integrate and inform the fight against Lyme disease and tick-borne disease globally.
(c) INTRODUCTION OF TICK-BORNE DISEASE WORKING GROUP FINDINGS AND RECOMMENDATIONS.—In carrying out this section, the Director of the Office shall, as directed by the Secretary, with any modifications made by and as otherwise determined appropriate by the Secretary, oversee and coordinate integration and implementation, into the activities of the Office and the activities and programs of the agencies and offices of the Department of Health and Human Services, of the recommendations to the Secretary and the findings and conclusions in the latest report of the Tick-Borne Disease Working Group submitted to the Secretary and congressional committees.

(d) PRIORITY BASED ON DISEASE BURDEN.—In carrying out this section, the Director of the Office shall give priority to Lyme disease and other tick-borne disease based on assessments of disease burden in the United States.

SEC. 3. NATIONAL STRATEGY.

(a) IN GENERAL.—The Secretary, in coordination with the Director of the Office, and in consultation with the Tick-Borne Disease Working Group, the agencies and offices of the Department of Health and Human Services, and other Federal agencies outside of the Department of Health and Human Services as appropriate, shall—
(1) not later than 2 years after the date of enactment of this Act, develop and submit to the Congress a national strategy for the conduct and support of Lyme disease and other tick-borne disease or disorder programs and activities; and

(2) not less than every 2 years thereafter, update such strategy.

(b) CONTENTS.—The strategy under subsection (a) shall include—

(1) proposed budgetary requirements;

(2) an assessment of all federally funded programs and activities related to surveillance, diagnosis, treatment, education, or prevention with respect to Lyme disease or other tick-borne disease, an evaluation of progress and performance based on mission and purpose, and a description of significant challenges or barriers to performance, including an assessment of Federal grants awarded;

(3) a strategy for improving diagnosis, treatment, and prevention, including increasing the impact of grants awarded by the National Institutes of Health, the Centers for Disease Control and Prevention, and other agencies and offices of the Department of Health and Human Services;
(4) a strategy for improving outcomes of individuals with Lyme disease or another tick-borne disease or disorder, including progress related to chronic or persistent symptoms and chronic or persistent infection and coinfections, including plans for evaluating the potential value of and supporting the conduct of observational studies, comparative effectiveness research, patient-centered outcomes research, or other real world evidence;

(5) the appropriate benchmarks to measure progress in achieving the improvements described in paragraphs (3) and (4);

(6) a strategy for improving interactions, coordination, and partnerships with other Federal agencies, State and local governments, and global entities; and

(7) the latest recommendations of the Tick-Borne Disease Working Group and the steps taken by the agencies and offices of the Department of Health and Human Services to implement those recommendations.
SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS, SURVEILLANCE, AND PREVENTION OF, AND RESEARCH ON, LYME DISEASE AND OTHER TICK-BORNE DISEASES AND DISORDERS.

(a) IN GENERAL.—The Secretary, in coordination with the Director of the Office, acting as the Secretary determines appropriate through the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Director of the Agency for Healthcare Research and Quality, the Administrator of the Health Resources and Services Administration, the Director of the Indian Health Service, and the heads of other Federal agencies, and in consultation with the Tick-Borne Disease Working Group, shall provide for—

(1) the conduct or support of the activities described in paragraphs (1) through (8) of subsection (b); and

(2) the coordination of all programs and activities of the Department of Health and Human Services related to Lyme disease and other tick-borne diseases and disorders and Bartonella.

(b) ACTIVITIES.—The activities to be conducted or supported under subsection (a)(1) consist of the following:

(1) EXPANSION AND ENHANCEMENT OF RESEARCH.—
(A) IN GENERAL.—The Secretary shall expand and intensify epidemiological, basic, translational, and clinical research regarding Lyme disease and other tick-borne disease and disorders and bartonellosis to better understand—

(i) the pathophysiology of Borrelia burgdorferi and other tick-borne microorganisms that are human pathogens and of Bartonella;

(ii) pathophysiological changes over time, including pathogen persistence profiles for patients with differing treatment histories;

(iii) activation and deactivation of immune system processes; and

(iv) whether, and what species of, Bartonella are transmitted by ticks.

(B) CLINICAL OUTCOMES RESEARCH.—The Secretary shall conduct or support clinical outcomes research to—

(i) establish epidemiological research objectives to determine the long-term course of illness for Lyme disease and other tick-borne diseases and disorders;
(ii) establish patient-centered treatment outcome objectives to allow for the comparative effectiveness of different treatment modalities; and

(iii) establish patient-centered research objectives to help elucidate promising treatment protocols for individuals suspected of harboring coinfections with more than one tick-transmitted pathogen.

(C) COLLABORATIVE, MULTIDISCIPLINARY RESEARCH.—The Secretary shall encourage the solicitation of proposals for collaborative, multidisciplinary research that would—

(i) result in innovative approaches to study emerging scientific opportunities or eliminate gaps in research to improve the research portfolio, including application of successful and promising advances in the study of other types of diseases, such as upregulating or downregulating immune system cells or processes;

(ii) outline key research questions, methodologies, and knowledge gaps;

(iii) expand the number of research proposals that involve collaboration be-
tween 2 or more national research institutes or national centers of the National Institutes of Health, including proposals for research through the Common Fund pursuant to section 402(b)(7) of the Public Health Service Act (42 U.S.C. 282(b)(7)) to improve the research portfolio;

(iv) expand the number of collaborative multi-institutional research grants related to tick-borne disease; and

(v) involve additional national research institutes and national centers of the National Institutes of Health in intramural and extramural research on tick-borne disease, such as the National Institute of Neurological Disorders and Stroke conducting or sponsoring research on neurologic Lyme disease.

(D) Evaluation.—Not later than 2 years after the date of enactment of this Act, the Secretary shall evaluate and make findings on—

(i) the feasibility and potential value to the research community of establishing a deidentified human subjects database for
Lyme disease and other tick-borne diseases and disorders;

(ii) existing government or private biorepositories for Lyme disease and other tick-borne diseases and disorders and whether—

(I) specimens and samples are adequate and available to meet researcher needs; or

(II) there are problems or challenges for researcher acquisition of samples and specimens; and

(iii) the scope and use of specimens and samples from cadavers, the questions and answers such research may provide, and the need for additional support of researchers using cadaver specimens.

(E) PRIORITY.—In carrying out this paragraph, the Secretary shall make it a priority to determine the extent of posttreatment persistence of Borrelia burgdorferi and the clinical significance of such persistence.

(2) DEVELOPMENT OF NEW AND IMPROVED DIAGNOSTIC TESTS.—
(A) IN GENERAL.—The Secretary, in co-
operation with the Director of the Office, and
acting through the Directors of the Centers for
Disease Control and Prevention and the Direc-
tor of the National Institutes of Health, shall
conduct and support research to—

(i) provide for the timely evaluation of
promising new and improved diagnostic
methods, including direct-detection tests,
antibody-based tests, and tests based on
biosignature and biomarker profiles to
make a specific diagnosis or aid in dif-
ferential diagnoses;

(ii) improve the sensitivity of Lyme
disease tests at all stages of disease pro-
gression;

(iii) develop a Lyme disease test capa-
ble of distinguishing between past and ac-
tive infections;

(iv) improve timely, sensitive, and spe-
cific diagnostic tools and tests for Rocky
Mountain spotted fever; and

(v) improve the performance (timeli-
ness and accuracy) of tools and tests for
other tick-borne diseases found in the United States.

(B) Strategies for expediting clearance.—The Secretary shall direct the Commissioner of Food and Drugs to design and propose or implement, as appropriate within the authorities and public health priorities vested in the Secretary by other provisions of law, strategies for facilitating and expediting the clearance or approval of improved diagnostic tests for Lyme disease and other tick-borne disease, particularly where—

(i) there are no cleared diagnostic tests; or

(ii) cleared diagnostic tests lack a high level of specificity or sensitivity or are unable to confirm the presence or absence of active infection.

(3) Ensuring safety and efficacy of vaccines.—The Secretary shall—

(A) ensure the safety and efficacy of any new, renewed, or modified human vaccine for Lyme disease, other tick-borne disease, or a combination of such diseases; and
(B) require the Commissioner of Food and Drugs to submit to the Secretary prior to final approval of the vaccine being reviewed, a report, with appropriate provisions for commercial confidentiality, detailing the safety of the vaccine and contrasting its safety profile based on its mechanisms of action to safety concerns expressed to the Food and Drug Administration regarding the human vaccine withdrawn from the market in 2002 and how those concerns with the withdrawn vaccine have been addressed or why they are not relevant.

(4) Monitoring and Understanding Human Cases of Lyme Disease and Other Tick-Borne Diseases.—

(A) In General.—The Secretary shall—

(i) establish and maintain a statistically sound, scientifically credible surveillance system to be known as the National Tick-Borne Disease Surveillance System; 

(ii) enhance and expand infrastructure and activities to track the epidemiology of Lyme disease and other tick-borne diseases and disorders; and
(iii) incorporate information obtained through such activities into the National Tick-Borne Disease Surveillance System.

(B) RESEARCH.—The Secretary shall ensure that the National Tick-Borne Disease Surveillance System is designed in a manner that facilitates further research on Lyme disease and other tick-borne diseases and disorders.

(C) CONTENT.—In carrying out subparagraph (A), the Secretary—

(i) shall provide for the collection and storage of information on the incidence and prevalence of tick-borne disease in the United States—

(I) while continuing to support activities in the 14 States with the highest number of reported cases of Lyme disease, and intensifying efforts in other States where Lyme disease has been reported and where all reported cases cannot be affirmatively associated with out-of-State travel in order to better determine where the disease is emerging;
(II) working with the States and
treating physicians, in consultation
with the Council of State and Terri-
torial Epidemiologists (in this clause
referred to as the “CSTE”), to im-
prove evaluation of the feasibility of
capturing data on cases that do not
meet surveillance criteria of the CSTE
and the Centers for Disease Control
and Prevention;

(III) in consultation with the
CSTE, working with States that are
using averaging or similar techniques
to estimate case reports to ensure that
data produced by that process are
able to be reported out by the Centers
for Disease Control and Prevention;

(IV) in consultation with the
CSTE, working with the States to en-
courage and improve laboratory re-
porting of Lyme disease and other
tick-borne diseases, and evaluate the
feasibility of creating a national uni-
form reporting system including man-
datory reporting by States and physicians and laboratories in each State;

   (V) including in the surveillance system bartonellosis transmitted by any vector and, if it is known, by the vector of transmission; and

   (VI) tracking incidence and prevalence data for tick-borne disorders;

and

(ii) to the extent practicable, shall provide for the collection and storage of other available information on Lyme disease and other tick-borne diseases and disorders, including information related to persons who have been diagnosed with and treated for tick-borne disease who choose to participate, such as—

   (I) demographics, such as age, race, sex, geographic location, and other information, as appropriate;

   (II) family history and experience with tick-borne disease or tick induced disorder;

   (III) history of exposure and known tick bites;
(IV) progression of signs and symptoms;

(V) diagnostic and treatment history and outcomes; and

(VI) additional screening conducted and related data, such as biological markers.

(D) CONSULTATION.—In carrying out this paragraph, the Secretary shall consult with individuals with appropriate expertise, which may include—

(i) epidemiologists with experience in disease surveillance or registries;

(ii) representatives of national patient advocacy and research organizations that focus on tick-borne disease and have demonstrated experience in research, data collection, or patient access to care;

(iii) health information technology experts or other information management specialists;

(iv) clinicians with expertise in Lyme disease or other tick-borne diseases or disorders; and
(v) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(E) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this paragraph.

(F) COORDINATION WITH FEDERAL, STATE, AND LOCAL AGENCIES.—Subject to subparagraph (H), the Secretary shall—

(i) establish agreements and mechanisms, as appropriate, for improved collecting and reporting of tick-borne disease surveillance data under subparagraphs (A), (B), and clause (i) of subparagraph (C) and other available information under clause (ii) of subparagraph (C) from community health centers funded by the Health Resources and Services Administration and medical facilities of the Indian Health Service;

(ii) establish formal agreements, as appropriate and may be worked out, to
provide for improved collection and reporting of surveillance data under subparagraphs (A), (B) or clause (i) of subparagraph (C) and other available information under clause (ii) of subparagraph (C), obtained from hospitals and medical clinics run by other Federal departments and agencies;

(iii) make information and analysis in the National Tick-Borne Disease Surveillance System available, as appropriate, to all components of the Department of Health and Human Services, to other Federal agencies, and to State and local agencies; and

(iv) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

(G) Public access.—Subject to subparagraph (H), the Secretary shall ensure that information and analysis in the National Tick-Borne Disease Surveillance System are available, as appropriate, to the public and other in-
terested parties on the website of the Department of Health and Human Services.

(H) **Privacy.**—The Secretary shall ensure that information and analysis in the National Tick-Borne Disease Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

(5) **Education and prevention.**—

(A) **Consumer and community education.**—The Secretary shall increase public education related to Lyme disease and other tick-borne diseases and disorders through the expansion of the community-based education programs of the Centers for Disease Control and Prevention to include development and publication of a consumer tick disease pamphlet, available online and by hard copy, addressing—

(i) ticks and tick-borne diseases common to the geographic area, tick-borne disease that could be acquired while on domestic or international travel, and ticks
that, while not common to the geographic area, could migrate to the area;

(ii) signs and symptoms of such tick-borne disease;

(iii) tick removal instructions;

(iv) the most effective actions individuals can take to reduce risk of exposure to ticks and risk of disease transmission; and

(v) additional community-based actions to reduce risk of exposure to ticks.

(B) COORDINATION.—In carrying out subparagraph (A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall coordinate with legally incorporated Lyme disease or other tick-borne disease organizations.

(C) DISSEMINATION.—The Administrator of the Health Resources and Services Administration and the Director of the Indian Health Service shall make available in rural health centers and clinics which they operate or fund—

(i) the consumer tick disease pamphlets developed under subparagraph (A); or
(ii) such other appropriate consumer
tick disease pamphlets as the Administra-
tion or Service may develop or acquire.

(D) PHYSICIAN EDUCATION.—The Sec-
retary shall carry out a physician education
program that addresses the full spectrum of sci-
entific research related to Lyme disease and
other tick-borne diseases and disorders, includ-
ing—

(i) the role of clinical diagnosis;

(ii) the limitations of serological diag-
nostic tests;

(iii) enhanced, validated diagnostics
available from laboratories certified under
section 353 of the Public Health Service
Act (42 U.S.C. 263a) that may aid the
physician;

(iv) guidelines available on the Na-
tional Guideline Clearinghouse;

(v) the voluntary nature of clinical
practice guidelines;

(vi) the complexities presented by co-
infections relating to symptomology, diag-
nosis, and treatment, including prudently
acting in the patient’s interest in non- or
low-incidence States; and

(vii) the identification of significant
research gaps most impacting diagnosis
and treatment, and significant research
being conducted to address those gaps.

(E) PROCESS FOR DEVELOPING PHYSICIAN
EDUCATION PROGRAM.—The Secretary of
Health and Human Services shall—

(i) conduct a public meeting to solicit
input for the design of the physician edu-
cation program under subparagraph (D);

(ii) give the public notice of such
meeting at least 45 days in advance;

(iii) also solicit input on the design of
the physician education program from the
Tick-Borne Disease Working Group;

(iv) publish a proposed syllabus for
the physician education program not more
than 120 days after the public meeting;

(v) allow for a 60-day public comment
period before publishing such syllabus in
final form; and

(vi) publish on the public website of
the Department of Health and Human
(6) MONITORING, UNDERSTANDING, AND CONTROLLING VECTORS AND ANIMAL RESERVOIRS OF LYME DISEASE AND OTHER TICK-BORNE DISEASE.—

(A) TICK SURVEILLANCE AND TESTING.—

The Secretary, in coordination with the Director of the Office, acting through the Director of the Centers for Disease Control and Prevention and other agencies and offices of the Department of Health and Human Services as appropriate, shall—

(i) not later than 180 days after the date of enactment of this Act, provide a report to the Congress describing the tick surveillance and pathogen testing activities of the Department and entities funded by the Department, including—

(I) a detailed description of the tick surveillance and tick pathogen testing activities and planned activities of the Vector-Borne Disease Regional Centers of Excellence as estab-
lished under Funding Opportunity Announcement RFA–CK–17–005, Catalog of Federal Domestic Assistance Number 93.084; and

(II) within such description, the roles of participating academic, governmental, and private institutions;

(ii) not later than 2 years after the date of enactment of this Act, in consultation and coordination with other Federal agencies and State and local government agencies, as appropriate, and established academic or nonprofit tick-testing centers, develop a framework and an implementation plan for a comprehensive nationwide strategy for the surveillance and testing of ticks for human pathogens and microorganisms with unknown pathogenicity, including a plan for a network of tick identification and testing laboratories;

(iii) not later than 2 years after the date of enactment of this Act, establish agreements and procedures for sharing data on surveillance and testing of ticks
with other Federal departments and agencies engaged in such activities; and

(iv) consult and coordinate with the American Veterinary Medical Association and the Companion Animal Parasite Council on obtaining and sharing data on the surveillance and testing of ticks and tick-borne pathogens, including geographic information from veterinary encounters.

(B) INVESTIGATION.—In carrying out subparagraph (A), the Secretary, in coordination with the Director of the Office, acting through the Director of the Centers for Disease Control and Prevention, in consultation and coordination with other Federal agencies that conduct or support tick surveillance or testing activities, as appropriate, and public and private laboratories, shall—

(i) investigate and, where appropriate, promote the use of advanced new technologies, such as tools to discover all known and all previously unidentified microorganisms in a vector; and

(ii) while being informed by previous surveillance studies, allow for the possi-
bility of rapid geographic migration of tick vectors and pathogens and unexpected findings.

(C) TICK CONTROL AND PREVENTION.—
The Secretary, in coordination with the Director of the Office, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall, as appropriate and pursuant to authorities vested in the Secretary by other provisions of law, support activities of and coordinate and share, information with other Federal, State, and local government agencies, involved or interested in tick prevention and control activities on—

(i) the development of safer and more effective tick repellents, both natural and chemical;

(ii) the use of acaricides or other chemical interventions;

(iii) nonchemical environmental measures to lessen human exposure to ticks;

(iv) genetic therapies for vectors or animal hosts to interfere with the life cycle of pathogens; and
(v) the development of vector or reservoir host vaccines.

(D) LEVERAGING EXISTING TICK MANAGEMENT RESOURCES.—In carrying out this paragraph, the Secretary, in coordination with the Director of the Office, acting through the Director of the Centers for Disease Control and Prevention, shall identify, build upon, leverage, and coordinate among existing tick surveillance, testing, and management resources and infrastructure wherever practicable.

(E) PUBLIC ACCESS TO DATA.—In carrying out this paragraph, the Secretary, in coordination with the Director of the Office, acting through the Director of the Centers for Disease Control and Prevention, in coordination and consultation with other Federal agencies and State and local agencies as appropriate, make data on tick surveillance, testing, control and prevention available to the public on the website of the Department of Health and Human Services.

(7) CONFERENCES, SYMPOSIA, SEMINARS, AND OTHER PUBLIC MEETINGS.—
(A) Sense of Congress.—It is the sense of the Congress that public meetings, conferences, symposia, and seminars (including webinars) sponsored by the Federal Government are a valuable input to strategic and operational programmatic planning within Federal agencies and to the work of the Tick-Borne Disease Working Group.

(B) Requirements.—The Secretary and the Director of the Office, in cooperation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Tick-Borne Disease Working Group, shall—

(i) no later than 24 months after the date of enactment of this Act, sponsor a state-of-the-science conference on Lyme disease and other tick-borne disease including identification of research gaps and top research priorities;

(ii) for any scientific or medical conference on Lyme disease or other tick-borne disease that is organized, sponsored, or paid for by the Department of Health and Human Services, ensure that a con-
trolling statement of work and significant modifications thereto, whether in the contract or as a separate document, issued to the vendor organizing or conducting the conference are in writing and made available to the public prior to the conference;

(iii) not later than 120 days after the conclusion of the conference under clause (i), make available a final report on the conference to the Tick-Borne Disease Working Group and to the public;

(iv) not later than 18 months after the date of enactment of this Act, working through the Director of the Agency for Healthcare Research and Quality, sponsor a symposium on the use of real-world evidence (meaning data from sources other than randomized clinical trials, such as observational studies, comparative effectiveness and patient-centered outcomes research, and patient clinical data or human subject data), including the standards and methodologies for collection and analysis of real-world evidence in managing Lyme disease and other tick-borne disease;
(v) include in such symposium identification and analysis of existing data sources, such as patient registries and human subjects' databases;

(vi) sponsor a researcher workshop on challenges and solutions for clinical trial design and implementation for Lyme disease to be held no later than 24 months after the date of enactment of this Act, which workshop may consider other tick-borne disease or coinfections with more than one tick-borne pathogen as may be feasible and practicable;

(vii) not later than 9 months after the date of enactment of this Act, in consultation with the Tick-Borne Disease Working Group, design a survey instrument or instruments targeted to patients and patient advocates, physicians and health care providers, and researchers regarding recommended subjects and agendas for federally sponsored meetings, conferences, and seminars, including webinars, on Lyme disease and other tick-borne disease;
(viii) not later than 6 months after the conduct of the survey, provide an analysis of the results of the survey to the Tick-Borne Disease Working Group and publish such results in the Federal Register for a 60-day public comment period; and

(ix) provide a final analysis and a proposed schedule and agenda for public meetings, conferences, and seminars, including webinars, for incorporation into the national strategy under section 3 as appropriate and to the Tick-Borne Disease Working Group.

(8) COMMON RESEARCH BIBLIOGRAPHY.—The Secretary, in coordination with the Director of the Office, shall direct the Director of the Agency for Healthcare Research and Quality to assemble a bibliography of peer-reviewed literature of tick-borne diseases and disorders in the United States, as well as for bartonellosis from whatever cause, appropriately organized for use by the scientific community, treating physicians, and the public. The bibliography should include literature relating to possible
mechanisms of persistent infection with Borrelia
burgdorferi or other types of Borrelia.

(c) PRIORITY BASED ON DISEASE BURDEN.—In con-
ducting and supporting activities under this section, the
Secretary shall give priority to Lyme disease and other
tick-borne diseases based on assessments of disease bur-
den in the United States.

SEC. 5. BIENNIAL REPORTS.

(a) IN GENERAL.—Not later than 24 months after
the date of the enactment of this Act, and biennially there-
after, the Secretary shall submit to the Congress a report
on the activities carried out under this Act and the activi-
ties of the Tick-Borne Disease Working Group.

(b) CONTENT.—Reports under subsection (a) shall
contain—

(1) a scientifically qualified assessment of Lyme
disease and other tick-borne disease, including a
summary of prevalence, geography, important expo-
sure characteristics, disease stages and manifesta-
tions or symptoms of those stages, based on a syn-
thesis of the broad spectrum of empirical evidence of
treating physicians, as well as published peer-re-
viewed data, to include for each tick-borne disease a
state-of-the-science diagnosis and treatment;
(2) a description of all programs and activities funded by the Department of Health and Human Services that are related to the surveillance, diagnosis, treatment, education, or prevention of Lyme disease or other tick-borne disease, and an evaluation of progress and performance based on mission and purpose, and discussion of significant challenges or barriers to performance, to include—

(A) for the initial report under this section, a description of the intramural and extramural research portfolios of the Centers for Disease Control and Prevention, the National Institutes of Health, and other agencies and offices of the Department of Health and Human Services which conducted or contracted for research projects related to Lyme disease or on other tick-borne disease or disorder, including information on—

(i) the award amount, institution, primary investigator, principal investigative question or questions, and significant conclusions; and

(ii) studies that received Federal funds and were terminated, in progress, or initiated in the fiscal year including the
date of enactment of this Act and the 5
prior fiscal years;

(B) for reports in subsequent years, all of
the information described in subparagraph (A),
except the reference in subparagraph (A)(ii) to
Federal funds terminated, in progress, or
awarded in the 6 prior fiscal years shall be
treated as reference to such funds in the 2 prior
fiscal years;

(C) a status and summary report on the
National Tick-Borne Disease Surveillance Sys-
tem, including—

(i) the type of information collected
and stored in the System;

(ii) the use, distribution, and avail-
ability of such information, including
guidelines for such use; and

(iii) the use and coordination of sur-
veillance and patient information data-
bases; and

(D) information on agreements, partner-
ships, cooperation, coordination, and data shar-
ing with external entities, such as State and
local governments, other Federal agencies,
working groups, and global entities;
(3) a description of major externally funded re-
search, surveillance, education, or other programs
and initiatives impacting the management or science
of tick-borne disease;

(4) recommendations for addressing research
gaps in scientific understanding of Lyme disease and
other tick-borne diseases and disorders and relevant
to development of effective diagnostic tools and
treatment protocols for Lyme disease and other tick-
borne diseases and disorders;

(5) a description of clinical practice guidelines
for any tick-borne disease published on the National
Guideline Clearinghouse;

(6) recommendations for addressing research
gaps in tick biology and tick management;

(7) a description of activities for the promotion
of public awareness and physician education initia-
tives to improve the knowledge of health care pro-
viders and the public in support of clinical and be-
havioral decision making in relationship to Lyme
disease and other tick-borne disease; and

(8) a copy of the most recent annual report
issued by the Tick-Borne Disease Working Group
and an assessment of progress in achieving rec-
ommendations of that Working Group.
(c) Biennial Reports of NIH.—The Secretary shall ensure that each biennial report under title III of the Public Health Service Act (42 U.S.C. 241 et seq.) or each triennial report under section 403 of such Act (42 U.S.C. 283) includes information on actions undertaken by the National Institutes of Health to carry out research with respect to Lyme disease and other tick-borne disease.

SEC. 6. DEFINITIONS.

In this Act:

(1) Bartonellosis.—The term “bartonellosis” means disease caused by Bartonella infection from any vector or source, unless otherwise specified.

(2) Disorder.—The term “disorder” means a disorder caused by ticks, but not inducing human infection, such as tick paralysis and Alpha-Gal meat allergy.

(3) Office.—The term “Office” means the Office of Oversight and Coordination for Tick-Borne Diseases established under section 2.

(4) Other Federal Agency.—Other Federal agency means a Federal Department, agency or office outside of the U.S. Department of Health and Human Services.
(5) Secretary.—The term “Secretary” means the Secretary of Health and Human Services.

(6) Tick-borne disease.—The term “tick-borne disease” means a disease that is known to be transmitted by ticks in the United States, unless otherwise specified, or that may be discovered to be transmitted by ticks in the United States.